

**HL7 SPL Working Group Process Communication Forum Telecon  
Wednesday, July 28, 2010**

Check out the SPL Working Group WIKI @:  
<http://spl-work-group.wikispaces.com>

**Questions on SPL:**

ER/DL regulatory questions? Send to [edrls@fda.hhs.gov](mailto:edrls@fda.hhs.gov)

SPL technical questions? Send to [spl@fda.hhs.gov](mailto:spl@fda.hhs.gov)

UNII or SRS questions? Send to [fda-srs@fda.hhs.gov](mailto:fda-srs@fda.hhs.gov)

**Agenda:**

**Image Quality [presentation by K Olger (and colleagues) from Perrigo]**

See handout for procedure. Some examples to check out: NDC 10768-7283\ NDC 45802-183

Q: Have you tried using any other software for image quality?

A: No – used in-house tools.

Q: Use of Corel X5 – improved create program. User recommends!

Corel X5 is the latest version. We use it over manual adjustments

Various tools mentioned: Adobe Reader (v9), Adobe Photoshop

Q: There are some graphics that are just too large. “What does it look like on a full screen?”

A: Huge cartons – worked with Lonnie and ended up splitting image into parts. You can ‘snapshot’ each half of the image. Put both images in a single section. Make sure that each image is tagged properly. Another way to cut size down some: Images of the whole carton minus the flaps

From Step by Step Instructions for SPL

**4.7 Content of labeling**

The content of the labeling provided with drug listing (e.g., professional labeling (package insert), consumer labeling, carton labels and container labels) is included in the same SPL file as the other drug listing information. Carton and container labels include the content of the Drug Facts or equivalent for animal drug products and the content of the Principal Display Panel including the image of the entire label as a single jpg file.

Q: 600 pixels wide – is this still a limitation?

A: Not any more. 1000 pixels was allowable.

Q: Doesn't that make the file too big (over 1MB)?

A: if we stick with 1000 on one of the sides, we've stayed under the 1MB limit.

Q: 96 dpi – still a limitation?

A: Not any more.

Q: Do you use the Trace program? Not yet.

Q: PNG (Portable Network Graphic) files – could the FDA consider this, as well?

A: For the larger files, FDA may need to consider alternate file formats.

For the PILLBOX graphics, NIH is using PNG file types.

Would like that FDA provide guidelines (but some dissenting opinions here). Consistent information for everyone would help.

### **ER/DL Recap:**

Last week, Paul Loebach attend (Team Lead from DRLS). Re-iterated that DRLS is willing to work directly with sponsors

The highlight from that meeting: An alternate way to delist paper-only listings

For Paper-only listings that need delisting, contact the DRLS via [edrls@fda.hhs.gov](mailto:edrls@fda.hhs.gov) and include the following: the product name, strength, NDC code, and company name.

**Note: Several people have tried this and had very quick responses and delistings!**

Note #2: This procedure will not remove any SPL that were filed in R3 and posted to DailyMed. For this, currently you will need to update the file in R4.

The minutes from the meeting will be placed on the WIKI and distributed to the subteam [after the DRLS group has a chance to review].

Next meeting scheduled for:

**Wednesday, Aug 11, 2010**

**Time: 1:00-2:30 ET**

**Dial-in info: number 1-877-423-2663**

**PIN# 517342**

- Minutes of previous Process Team meetings are here:  
<http://spl-work-group.wikispaces.com/Process+Communications+Forum>